IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,	)	
Plaintiffs,	)	
v.	)	No. 1:18-cv-02084-RC
ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, *et al.*,	)	
Defendants.	)	

DEFENDANTS' OPPOSITION BRIEF ON REMEDY

INTRODUCTION

The Court determined that the U.S. Department of Health and Human Services ("Agency") acted in an ultra vires fashion when it reduced the payment, in the 2018 Medicare Outpatient Prospective Payment System Rule ("OPPS Rule"), 82 Fed. Reg. at 52, 362, for drugs purchased through the 340B Program. Memorandum Opinion ("Op."), Dec. 27, 2018, ECF No. 25. The Court, however, declined to issue a remedy without further briefing, as it recognized that the remedy in this case could potentially wreak havoc on the vast and complex Medicare payment system. *Cf.* Op. at 35. That concern was well placed. As the Agency explained in its opening brief, vacating the 2018 OPPS Rule would disrupt the entire Medicare outpatient payment system, affecting the Agency, providers, and beneficiaries alike – and compelling the agency to review and reassess more than 110 million claims. HHS Remedy Br., ECF No. 31, Jan. 31, 2019, at 8-9. In many cases, beneficiaries would end up paying more after this reassessment than would otherwise have been the case. Remand without vacatur minimizes hardships to beneficiaries and providers. It is the proper remedy: It would allow the Agency to use its expertise to select the optimal remedy (including the optimal payment calculus) in light of all of the competing interests in the vast system it administers. *Id.* at 10-11. It would give effect

to this Court's ruling while allowing the Agency to maintain budget neutrality, as required, and minimizing disruption and hardships to beneficiaries.[1]

Plaintiffs argue for a different approach, but their argument is unpersuasive. Plaintiffs seek an injunction requiring the Agency to pay the 340B hospitals pursuant to a particular payment amount specified in their brief. But D.C. Circuit precedent is clear: In a circumstance such as this, an injunction imposing specific duties on the agency is improper. Rather, a court is to remand the matter to the agency for it "to decide in the first instance how best to provide relief." *Bennett v. Donovan*, 703 F.3d 582, 589 (D.C. Cir. 2013). This deference principle is particularly compelling in the area of Medicare given the "substantial deference that Courts owe to the Secretary [of Health and Human Services] in the administration of such a 'complex statutory and regulatory regime.'" *Shands Jacksonville Med. Ctr., Inc. v. Azar*, 2018 WL 6831167, at *13 (D.D.C. Dec. 28, 2018) (quoting *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 404 (1993)). Plaintiffs cite several cases which they contend support their entitlement to the particular payment amount they advance, but none imposes the kind of mandatory injunction plaintiffs seek here. Finally, contrary to plaintiffs' assertions, budget neutrality is inextricably linked to the policy in question and is therefore relevant to the issue of remedy. The budget neutrality requirement significantly increases the disruptiveness of vacatur, and militates in favor of remand without vacatur.

ARGUMENT

I. Remand Without Vacatur Is the Appropriate Remedy

In this case, the proper remedy is for the Court to remand the matter to the agency without vacating the 2018 OPPS Rule. *See* HHS Remedy Br. at 10-11. When a district court reviewing agency action identifies a non-harmless flaw in an agency rule, the standard remedy is to remand the matter to the agency because, in this situation, the district court is acting as an appellate tribunal. *Northern Air Cargo v. U.S. Postal Serv.*, 674 F.3d 852, 861 (D.C. Cir. 2012).

[1] By advocating for remand without vacatur, Defendants do not waive their appellate rights. *See Occidental Petroleum Corp. v. S.E.C.*, 873 F.2d 325, 330 (D.C. Cir. 1989).

A court can choose to vacate a rule in conjunction with remanding it only after it has conducted a vigorous analysis of the propriety of doing so by examining both the seriousness of the alleged flaw in the rule and the potentially disruptive consequence of vacatur. *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150–51 (D.C. Cir. 1993). Applying that two-part test here, vacatur is not warranted here. Among other things, vacatur would greatly disrupt the complex system for paying Medicare claims for outpatient care. It would introduce problems with the statutory budget neutrality requirement that would necessitate the entire OPPS to be recalculated for 2018, affecting the more than 110 million OPPS claims the Agency expect to process for 2018. *See* Declaration of Elizabeth Richter, Jan. 31, 2019, ¶¶ 3, 7 (attached to HHS Remedy Br.). This could (1) require HHS to recoup money from Medicare providers, (2) obligate some Medicare beneficiaries to be responsible for more cost-sharing for past services already rendered and paid for, and (3) delay ongoing payments to Medicare providers, potentially disrupting the receipt of services by beneficiaries. HHS Remedy Br. at 8-9. Remand without vacatur is the most prudent option. It affords the Agency an opportunity to craft a remedy in the first instance, which is consistent with the "substantial deference that Courts owe to the Secretary [of Health and Human Services] in the administration of such a 'complex statutory and regulatory regime.'" *Shands Jacksonville Med. Ctr*, 2018 WL 6831167, at *13 (quoting *Good Samaritan Hosp.*, 508 U.S. at 404).

II. D.C. Circuit Precedent Forecloses Plaintiffs' Argument that Court Should Issue an Injunction Imposing Specific Duties on the Agency

Plaintiffs argue that the Court should issue an injunction "order[ing] HHS to recalculate payments due to 340B hospitals for 2018 claims to ensure that those hospitals receive payment based on the statutory rate of ASP [average sales price] plus 6 percent provided by the 2017 OPPS rule." Pl. Remedy Br. at 2. Plaintiffs continue by noting that "[h]ospitals that have already received payment for 340B claims using the 2018 methodology should receive a supplemental payment for those claims in an amount that equals the amount they received and the amount they are entitled to (based on the ASP + 6% methodology)" and that "[h]ospitals that

have not received payment for 340B claims should receive . . . the amount they would have received under the 2017 OPPS rule . . . ." *Id.* at 2-3. Finally, plaintiffs suggest that the Court could specify the precise mechanism by which these payments will be made. Id. at 3-4 (discussing CMS's National Claims History database and how it purportedly could be used to make the payments plaintiffs' seek).

This proposal is contrary to bedrock principles of administrative law. To start, with one exception not applicable here,[2] an injunction requiring an agency to take a specific action is not an appropriate remedy for an unlawful agency rule. D.C. Circuit precedent makes this point clear. For example, in *Bennett v. Donovan*, 703 F.3d 582, 589 (D.C. Cir. 2013), plaintiffs challenged a reverse-mortgage regulation issued by the U.S. Department of Housing and Urban Development ("HUD"). After laying out a series of administrative steps that HUD *could* take to remedy plaintiff's injury, the D.C. Circuit emphasized: "We do not hold, of course, that HUD is *required* to take this precise series of steps, nor do we suggest that the district court should issue an injunction to that effect. Appellants brought a complaint under the Administrative Procedure Act to set aside an unlawful agency action, and in such circumstances, it is the prerogative of the agency to decide in the first instance how best to provide relief." *Id.*

Northern Air Cargo v. U.S. Postal Serv., 674 F.3d 852, 861 (D.C. Cir. 2012), similarly demonstrates this agency-deference principle, which is not limited to cases arising under the APA. Plaintiffs in that case challenged actions of the U.S. Postal Service, to which the APA does not apply. *Id.* at 860. The district court entered an injunction against the Postal Service. It should not have, the D.C. Circuit explained: "It was quite anomalous to issue an injunction. When a district court reverses agency action and determines that the agency acted unlawfully, ordinarily the appropriate course is simply to identify a legal error and then remand to the agency, because the role of the district court in such situations is to act as an appellate tribunal."

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[2] The exception is when there is only one possible choice that the Agency can take on remand. *See Berge v. United States*, 949 F. Supp. 2d 36, 42-43 (D.D.C. 2013) . That is not the case here. There is more than one way the Agency could address the error found by the Court, as noted in defendants' opening brief. HHS Remedy Br. at 10-11.

Id. at 861. *See also Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005) ("Thus, under settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the correct legal standards. Accordingly, the district court had jurisdiction only to vacate the Secretary's decision rejecting the hospital's revised wage data and to remand for further action consistent with its opinion. It did not, as the hospital contends, have jurisdiction to order either reclassification based upon those adjusted wage data or an adjusted reimbursement payment that would reflect such a reclassification.") (quotation marks and citation omitted from parenthetical).

The holdings of *Bennett*, *Northern Air Cargo*, and *Palisades General Hospital* squarely apply to this case. The Court determined that HHS acted unlawfully when it reduced the payment rate for drugs purchased through the 340B Program in the 2018 OPPS Rule. But the remedy is not to issue an "anomalous" injunction requiring the Agency to take a precise series of steps on remand – such as to pay claimants for specific claims under the 2017 rule by a particular application of the National Claims History database as plaintiffs suggest.[3] Instead, under the APA and federal common law administrative principles, the Court should defer to the "agency to decide in the first instance how best to provide relief." *Bennett*, 703 F.3d at 589. This is particularly the case where, as here, there is more than one remedial option available to the

[3] Moreover, plaintiffs' proposed approach of using the National Claims History database to make lump-sum payments on a hospital-by-hospital basis is not the ordinary, normal course of business for the Medicare system. And such a departure could have unintended consequences for a system that normally operates on a claim-by-claim basis, which the agency would need to consider in the context of a remand. CMS normally records the amount of Medicare payment for a particular service on a claim-by-claim basis, which is then used in subsequent administrative appeals filed by Medicare beneficiaries and providers; such payment amount is used by private insurers that are responsible for cost-sharing amounts following the Medicare payment determination, *see* 42 U.S.C. § 1395u(h)(3)(B); and more generally such amounts are used by Medicare managed care plans and other insurance programs that follow Medicare payment rates. The hospital-by-hospital payment approach advanced by plaintiffs does not sufficiently account for the fact that, in general, the amount of Medicare payment for a particular item or service is ordinarily, customarily reflected on the actual claim for Medicare benefits.

Agency, as explained in defendants' opening brief. The Agency could choose to provide retrospective relief and tackle the significant operational difficulties of redoing all of the 2018 claims, or it could choose to provide a prospective payment increase for the purchase of 340B drugs as proxy for the past underpayment identified by the Court, *see, e.g.*, *Shands Jacksonville Med. Ctr*, 2018 WL 6831167, at *13 (approving a prospective remedy). Or it could choose something else once it has had an opportunity to assess the competing equities and interests. The important point is that under D.C. Circuit precedent the choice about how to provide relief should belong to the Agency, especially in the context of the Secretary's administration of the complex Medicare system, which processes millions of claims and pays billions of dollars.

There are several other flaws with plaintiffs' proposal. First, it assumes that plaintiffs' have an entitlement to the payment rate used in 2017. Pl. Remedy Br. at 3 (arguing that plaintiffs "should receive the full amount to which they are entitled (the amount they would have received under the 2017 OPPS rule)"). But the Court did not hold as much. To the contrary, while the Court rejected the adjustment made by the Agency, it recognized that the Agency had the authority to make some adjustments under the statute. Op. at 28 (noting that the "Secretary is permitted to make 'adjust[ments]' to those rates for whatever reasons he deems 'necessary'"). Thus, plaintiffs' requested injunction is improper because it assumes that the Secretary would not have exercised such authority in the absence of the 2018 OPPS Rule. Indeed, on remand to determine the appropriate the remedy in the first instance, the Agency would not need to assume that the 2017 OPPS payment rate is the baseline from which any remedy must be fashioned.

Second, plaintiffs' proposal requests an inappropriately broad injunction. More specifically, it asks the Court to "order HHS to recalculate the payments due to 340B hospitals . . . ." Pl. Remedy. Br. at 2. But plaintiffs have not demonstrated that they represent all 340B hospitals. The Supreme Court has held that a "plaintiff's remedy must be limited to the inadequacy that produced his injury in fact" and that "the Court's constitutionally prescribed role is to vindicate the individual rights of the people appearing before it." *Gill v. Whitford*, 138 S. Ct. 1916, 1930 (2018). It has also held that an injunction should be no broader than that necessary to

provide a plaintiff relief, *Madsen v. Women's Health Ctr., Inc*., 512 U.S. 753, 765 (1994). Plaintiffs' request for an injunction that would benefit non-plaintiffs is, therefore, overly broad and should be denied for that reason as well.

III. The Cases Cited By Plaintiffs Undercut Their Argument

Plaintiffs cite three cases – *Cape Cod Hospital v. Sebelius*, 630 F.3d 203 (D.C. Cir. 2011), *H. Lee Moffitt Cancer Center & Research Institute Hospital, Inc. v. Azar*, 324 F. Supp. 3d 1 (D.D.C. 2018), and *Shands Jacksonville Medical Center v. Burwell*, 139 F. Supp. 3d 240 (D.D.C. 2015) – for the proposition that "courts and HHS have provided comparable remedies." Pl. Remedy. Br. at 4 (initial capitals removed). But, in fact, in none of those cases did the court issue the sort of mandatory injunction that plaintiffs seek here.

Cape Cod Hospital is no help to plaintiffs. In *Cape Cod Hospital*, the Court concluded that HHS had failed to explain that it had properly accounted for a wage adjustment in several Inpatient Prospective Payment System ("IPPS") Rules. 630 F.3d at 214-16. But the court did not order the Agency to adopt a specific wage adjustment calculated in a manner prescribed by the court, which is the analog to what plaintiffs here seek. Instead, recognizing that the agency should decide in the first instance how best to provide relief, the court "remand[ed] for CMS either to *explain* why reversing all prior rural-floor budget-neutrality adjustments was unnecessary to achieve budget neutrality in 2008 or, if it can provide no explanation beyond the finality concern we have rejected here, to recalculate the payments due the hospitals under *a formula* that removes the effects of the prior rural-floor budget-neutrality adjustments." *Id.* at 216 (emphasis added).

H. Lee Moffitt Cancer Center stands for the same proposition. In that case, the court decided that HHS had improperly delayed a payment adjustment due to cancer hospitals. *H. Lee Moffitt Cancer Center*, 324 F. Supp. 3d 13-18. Plaintiffs there requested that the court "(a) vacate the provisions of the . . . rulemaking that set an effective date of January 1, 2012, for the cancer-hospital adjustment, (b) direct HHS to change the effective date to January 1, 2011, and

(c) require HHS to adjust Moffitt's payments for its 2011 and 2012 fiscal years accordingly." *Id.* at 18-19. But the court "den[ied] Moffitt's motion to the extent it [sought] any of that specific relief," and instead "simply remand[ed] to HHS so that it [could] consider and adopt an 'appropriate adjustment' for the 2011 calendar year." *Id*. at 19. This decision does not support plaintiffs' request for an "anomalous" mandatory injunction requiring the Agency to reimburse 340B Program drugs at a rate specified in the injunction. *Cf. Northern Air Cargo*, 674 F.3d 861.

Shands Jacksonville Medical Center also undercuts plaintiffs' argument. In that case, the court concluded that the HHS had instituted an across-the-board reduction of 0.2% on the payment rate for IPPS without providing an appropriate opportunity for public comments. *Shands Jacksonville Med. Ctr*., 139 F. Supp. 3d at 265. The Court did not, however, remedy that identified flaw by ordering the agency to retroactively institute an across-the-board increase of 0.2%. Instead, based on the *Allied-Signal* factors discussed at the outset of this section, it simply remanded the matter to the Agency, without vacatur. *Id.* at 270-71. The same remedy is warranted here. HHS Remedy Br. at 10-11.[4]

[4] Plaintiffs also argue that "HHS has acknowledged that the Hospital Plaintiffs and member hospitals of Association Plaintiffs are entitled to reimbursement if plaintiffs prevailed on the merits." Pl. Remedy Br. at 7. Defendants do not deny that the Court's order entitles plaintiffs to a remedy, and that (if the Court's order is not altered or reversed in any further proceedings) the remedy will comprise some form of compensation for the 2018 payment rate reduction for drugs purchased through the 340B Program. But, as noted throughout, the exact remedy should be selected, in the first instance, by the Agency. And defendants have not stated otherwise. The language quoted by plaintiffs in their brief states that "'*if* Plaintiffs hypothetically were to prevail and obtain an order directing Defendants to reinstate the ASP+6% OPPS payment rate for 340B drugs, they could seek payment for their Medicare claims under the higher ASP+6% rate in a variety of ways.' " Pl. Remedy Br. at 7 (quoting *Am. Hosp. Ass'n v. Hargan*, No. 17-2447, ECF. No. 18 at 49 (D.D.C.)). The key to this passage is the first word: if. The passage does not say that plaintiffs are entitled to an order reinstating the ASP + 6% payment rate for drugs purchased through the 340B Program in 2018, but that "if" they obtained such an order, they could recover their money through a variety of procedural mechanisms. This is an important difference, one that recognizes discretion left to agency to craft a remedy, be it retroactive payments of individual claims, a prospective payment rate increase as proxy for the past reduction, or something else.

IV. Budget Neutrality Applies and Supports Remand Without Vacatur

Lastly, plaintiffs make a series of arguments about budget neutrality. All are flawed.

As an initial matter, an injunction is an equitable remedy – the scope of which should be guided by equitable principles – and plaintiffs' proposed remedy is inequitable on its face. Plaintiffs request to be paid for 340B-acquired drugs under the 2017 policy, but retain the inflated 3.2% conversion factor in the 2018 rule. Such a remedy would be inequitable. The budget neutrality adjustment at issue here was part and parcel of the 340B payment adjustment that plaintiffs contested. That is, absent the 340B payment adjustment, CMS would not have made the associated budget neutrality adjustment to offset the decreases in payments that would have otherwise occurred under the OPPS. The budget neutrality adjustment had the effect of increasing the payment rates for *all* non-drug OPPS services – including those furnished by the plaintiff hospitals themselves – which they simply ignore when they ask solely for the 340B drug claims payment amounts to be increased. Such a remedy is not equitable.

As to plaintiffs' specific contentions, first they argue that "[b]udget neutrality is not a barrier to the relief sought here." Pl. Remedy Br. at 8. But defendants have not argued that budget neutrality obviates the ability of plaintiffs to get a remedy. Instead, defendants have argued that the budget neutrality requirement increases the disruption that would be caused by vacatur of the 2018 OPPS Rule. HHS Remedy Br. at 6-8. And as explained in defendants' opening brief, the scope of this potential disruption demonstrates that the appropriate remedy would be for the Court to remand the matter without vacating the 2018 OPPS Rule.

Second, plaintiffs contend that "there is a serious question as to whether even HHS's initial change to reimbursement for 340B drugs was subject to budget neutrality" because "HHS made that change pursuant to 42 U.S.C. § 1395l(t)(14) rather than 42 U.S.C. § 1395l(t)(9), and only the latter provision references budget neutrality." Pl. Remedy Br. 8. To that point, they note that the Agency's appellate counsel stated, at oral argument, that it was not clear that the government would contend that "all adjustments need to be budget neutral under [(t)]14." *Id.* at 9 (quoting) Oral Arg. Tr. 34:6-7, *Am. Hosp. Ass'n v. Azar*, No. 18-5004, Docket No.1770299.

Contrary to plaintiffs' contention, the statutory budget neutrality requirement applied to the adjustment in the 2018 OPPS Rule. For one thing, the Agency made the adjustment under § 1395l(t)(9) in addition to (t)(14), 82 Fed. Reg. at 52,356, and plaintiffs admit that (t)(9) is subject to budget neutrality, Pl. Remedy Br. at 8. For another, pursuant to 42 U.S.C. § 1395l(t)(14)(H), any adjustments made by the Secretary to payment rates using the formula outlined in paragraph (t)(14)(A)(iii) of the statute are subject to the general budget-neutrality requirements outlined in paragraph (t)(9) (subject to an express exception for 2004 and 2005) – a point that the Agency made following the appellate argument in a letter under Federal Rule of Appellate Procedure 28(j). *Am. Hosp. Ass'n v. Azar*, No. 18-5004, Docket No.1730366, May 10, 2018. And, of course, as a factual matter, the Agency applied budget neutrality, increasing the payment rate for all items and services (other than drugs) by 3.2% or approximately $1.6 billion. 82 Fed. Reg. at 52,623. This payment increase for non-drug items and services was applied uniformly across the OPPS, including for services rendered by plaintiffs themselves.

Third, plaintiffs assert that "expenditures need not be budget neutral when they fix a prior, improper underpayment." Pl. Remedy Br. at 9. As support they point to a regulation that applies to the correction of wage indices, 42 C.F.R. § 412.64(k), and argue that the statute applies the budget neutrality requirement only to certain adjustments, which would not include the change to the payment rate for 340B Program drugs that the Agency made in 2018. Pl. Remedy Br. at 9.

The regulation that plaintiffs cite, 42 C.F.R. § 412.64(k), does not undercut the conclusion that budget neutrality applies. That regulation governs wage-index adjustments for hospitals (which might be necessary, for example, if a Medicare contractor incorrectly performs some wage calculations), and does not address whether budget neutrality applies to an approximately $1.6 billion adjustment to all of the payment rates in an OPPS rule. As the Agency appropriately concluded in the 2018 OPPS Rule, it does. See, e.g., 42 U.S.C. § 1395*l*(t)(14)(H); 82 Fed. Reg. at 52,623. Similarly, plaintiffs' argument that increasing the payment rate for drugs purchased through the 340B Program would not constitute an

"adjustment" under the statute is flawed. As defendants have explained, plaintiffs are not entitled to an injunction ordering that the Agency increase the payment rate for 340B Program drugs. Rather, any additional compensation to plaintiffs should result from the Agency issuing a rule to conform the payment rate for such drugs to the Court's reading of the statute. And if the rule is retroactive, then the increase in payment will be an "[a]dditional expenditure[ ] resulting from this paragraph . . . [that] shall be taken into account . . . " in determining the payment rate for all other covered items and services in a budget neutral fashion. 42 U.S.C.A. § 1395*l*(t)(14)(H).

Fourth, plaintiffs argue that "[i]n *H. Lee Moffitt Cancer Center and Research Institute Hospital*, the court determined that HHS could make retroactive adjustments, possibly even without corresponding changes elsewhere, without running afoul of the budget-neutrality requirement," *id.*, and that "[l]ikewise, in the present case, HHS should be able to make retroactive payments pursuant to a court order (to remedy its illegal behavior) without running afoul of any budget neutrality requirement if one exists," *id.* at 10.

H. Lee Moffitt Cancer Center does not undercut the conclusion that budget neutrality applies. The court in that case first noted that the budget neutrality principle did not alter whether the Agency acted contrary to law. *H. Lee Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 15. But defendants here are not arguing that budget neutrality considerations should affect the Court's decision about whether the Agency's adjustment complied with the statute, rather, defendants argue that budget neutrality considerations relate to this Court's upcoming remedial decision – and militate against vacatur. The *H. Lee Moffitt Cancer Center* court also suggested that any budget neutrality concerns could be cured by the Agency through recoupment. *Id.* ("While the most logical way to carry out the statute's budget-neutrality mandate is to decrease rates prospectively for the upcoming year, nothing says that is the only way."); *see also id*. at 17 n. 5 ("The adjustment could theoretically have a retroactive impact on private parties, if the government decided that budget neutrality demanded clawing back funds to other hospitals for the services rendered during the 2011 calendar year."). Nonetheless, as Defendants explained in

their opening briefing, given the number of claims at issue, recoupment would be a highly disruptive process. *See* HHS Remedy Br. at 8-9. Finally, the court in *H. Lee Moffitt Cancer Center*, a case which involved a delay in payments to 11 cancer hospitals, noted that in another situation HHS authorized a purported retroactive adjustment to 10 or so rural hospitals in the 2007 OPPS Rule without making any offsetting recoupments. *Id.* at 15-16; *see* 71 Fed. Reg. 67960, 68010. But the Agency's decision, in the context of the rural hospital adjustment, about whether to upend millions of claims decisions to recoup funds from thousands of hospitals to offset additional payments to 10 or so rural hospitals – while incurring significant administrative costs to do so, *cf.* Richter Decl. ¶ 7 – does not undercut the Agency's expert judgment that a retroactive upward adjustment in the neighborhood of *$1.6 billion*, which *does* affect all Medicare providers, would require an offsetting recoupment to satisfy the statutory budget neutrality requirement. *Cf. H. Lee Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 16 (distinguishing that case, which concerns a single adjustment applied to 11 cancer hospitals, from cases involving adjustments to prospective payment rates).

Fifth and finally, plaintiffs argue that "budget neutrality would play no role if individual hospitals used the administrative process to successfully obtain full payment on 340B claims that HHS had illegally withheld." Pl. Remedy Br. at 10. This assertion is false. The choice of the mechanism for providing additional compensation does not change the fact that an upward adjustment of the scope at issue here would require an offsetting change to comply with the statutory budget neutrality requirement.[5]

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[5] The Federation of American Hospital's (FAH's) amicus brief argues that budget neutrality only binds the Agency prospectively and that the Agency lacks the ability to recoup money to achieve budget neutrality, should it act retroactively. Amicus Br. of the FAH, ECF No. 33, Feb. 7, 2019, at 5-6, 7-10. Both assertions are wrong. The D.C. Circuit has not adopted the view that budget neutrality is prospective only. In *Amgen, Inc. v. Smith*, the Court explained that while "[p]ayments to hospitals are made on a prospective basis . . . given the length of time that review of individual payment determinations could take, review could result in the retroactive ordering of payment adjustments after hospitals have already received their payments for the year" and that " both the pass-through and equitable adjustments to payment rates are subject to a budget-neutrality requirement under § (t)(2)(E), such that judicially mandated changes in one payment

CONCLUSION

The Court should remand this matter to the Agency without vacatur, and permit the Agency to determine in the first instance what remedial measures are appropriate and at what pace and manner. The Court should deny plaintiffs' other remedial requests. If the Court vacates 2018 OPPS Rule, or grants any of plaintiffs' other remedial requests, then defendants request that the Court stay the order to afford the Solicitor General sufficient time to decide whether to pursue appeal. 28 C.F.R. § 0.20(b); 28 U.S.C. § 2107(b).

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Respectfully submitted,

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rate would affect the aggregate impact of the Secretary's decisions *by requiring offsets elsewhere* . . . ." 357 F.3d 103, 112 (D.C. Cir. 2004) (emphasis added). Moreover, the Agency has the authority to recoup funds should it need to do so. *See, e.g.*, 42 C.F.R. § 405.980 (reopening of Medicare initial determination); 42 C.F.R. Part 401, Subpart D (reporting and returning of Medicare overpayments).